



Office of the Chairman

DCI/IC 78-2824/1

JUN 29 1978

MEMORANDUM FOR: Director of Central Intelligence

FROM: Ambassador Edward S. Little
Chairman, Human Resources Committee

SUBJECT: Guidelines for Human Subject Research
Within the Intelligence Community

1. (U) Action Requested: Your (a) approval of a decision to terminate the on-going initiative to publish "Guidelines for Human Subject Research Within the Intelligence Community" (proposed [redacted]), and (b) signature of a letter responding to an inquiry from the Chairman of the Senate Select Committee on Intelligence on this subject.

2. (U) Background:

a. The initiative to publish a Community directive on this subject began shortly after Executive Order 11905 was issued. That Executive Order restricted experimentation with drugs only and inaccurately stated that such experimentation must be in accordance with guidelines issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Executive Order 12036 corrected this error. It states "No agency within the Intelligence Community shall sponsor, contract for, or conduct research on human subjects except in accordance with guidelines issued by the Department of Health, Education, and Welfare. The subject's informed consent shall be documented as required by those guidelines."

b. Despite this, there was sufficient support in the Community for us to proceed with the development of Community guidelines. NFIB agencies contributed to and supported the proposed guidelines through the NFIB mechanism. A proposed DCID 1/13 was recently cleared with NFIB agencies (Tab B).

c. In the final coordination process [] of the Office of General Counsel (OGC) non-concurred, expressing the view that the proposed DCID is neither needed nor appropriate. (Comments at Tab C). I now agree with [] that a DCID is not necessary and that it can be dropped. The General Counsel correctly makes the point that agencies must implement the Executive Order which refers them to specific guidelines formulated by the Department of Health, Education and Welfare. More importantly, however, the publication of the proposed directive would not contribute constructively in guiding human subject research in the Intelligence Community. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research is now able to monitor the guidelines of the various departments and agencies. Also, with the passage of time, public affairs advantages of this initiative appear fewer. The clarity and directness of the operative statement in the Executive Order lead me to recommend not publishing community guidelines.

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d. Senator Inouye's letter to you asked for a copy of the proposed Community guidelines as well as views of the NFIB on a few procedural matters (Tab D). Your interim response (also at Tab D) stated that the guidelines were being coordinated and would be provided when completed. The proposed letter to Senator Bayh explains why it was decided not to issue a DCID.

e. The National Commission has seen and commented on an early version of the Community guidelines. The CIA regulation on this subject has not been drafted; it was held in abeyance pending the outcome of the DCID. I assume the Agency will now proceed to draft and issue an appropriate regulation.

f. If you approve recommendations a and b below, we will notify the National Commission of your decision.

3. (U) Recommendations:

a. You approve dropping the proposed "Guidelines for Human Subject Research Within the Intelligence Community."

b. You sign the proposed letter to Senator Birch Bayh (Tab A).



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Recommendation a:

Approve _____ Disapprove _____

Attachments:

- Tab A - Proposed letter to Senator Bayh
- Tab B - Initial submission for [] including forwarding memorandum and Agencies' comments.
- Tab C - Comments on DCID 1/13 from [] (OGC)
- Tab D - Senator Inouye's letter

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CONCUR:

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DCI/IC/OPEI/HRD/[]azi (28 June 1978) Ext. 1225

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The Director of Central Intelligence

Approved For Release 2004/08/19 : CIA-RDP81M00980R000100020031-5

OCT 11 1978

The Honorable Birch Bayh
Chairman, Senate Select Committee
on Intelligence
Russell Senate Office Building - Room 363
Washington, D.C. 20510

Dear Mr. Chairman:

This is in follow-up of my letter on human subjects research to Senator Inouye dated 5 October 1977. Last September he had asked us to provide a copy of the draft "Guidelines for Human Subject Research Within the Intelligence Community." My letter informed the Senator that the Intelligence Community was reviewing a final draft of the guidelines, and that the draft would be provided later.

In the course of coordinating the guidelines, it was determined that a Community directive is not actually required. Executive Order 12036, Section 2-302 states that "No agency within the Intelligence Community shall sponsor, contract for, or conduct research on human subjects except in accordance with guidelines issued by the Department of Health, Education and Welfare. The subject's informed consent shall be documented as required by those guidelines." The clarity and directness of the Executive Order on this matter have led us to conclude that a Community directive is not necessary or appropriate.

The Executive Order, of course, is binding for all agencies of the Intelligence Community. Individual departments and agencies conducting research on human subjects have or will soon publish departmental directives for the implementation of the Executive Order. The internal directive of CIA will be forwarded to you as soon as it is completed.

Yours sincerely,

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STANSFIELD TURNER

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DIRECTOR OF CENTRAL INTELLIGENCE
Human Resources Committee

28-15381
DEC 78-2742
7-27-78

Office of the Chairman

DCI/IC 78-2824

28-15381

MEMORANDUM FOR: Director of Central Intelligence

FROM:

[REDACTED]
Chairman, Human Resources Committee

SUBJECT: Guidelines for Human Subject Research within the
Intelligence Community

1. (U) Action Requested: Approval of proposed [REDACTED]
"Guidelines for Human Subject Research within the Intelligence
Community." (Attachment 1)

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2. (U) Background:

a. The initiative to publish a Community directive on this subject was begun by this office shortly after Executive Order 11905 was issued. The former Executive Order in restricting experimentation incorrectly stated that human subject research would be in accordance with guidelines issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research rather than the Department of Health, Education and Welfare (DHEW). Executive Order 12036 corrects this error.

b. Over the past twelve months, development of a directive has involved NFIB, the National Commission, and the DHEW. In November of last year the guidelines were circulated to NFIB members for their comment. The proposed draft incorporates most of the changes proposed by members. These changes are underlined in the text of the guidelines; the submitting agency is indicated in the margin. Changes proposed by agencies, but not incorporated into the DCID, are summarized in Attachment 2. A comment is offered as rationale for not incorporating these proposals. Complete comments of individual agencies are also provided. (Attachment 3)

c. The publication of an Intelligence Community directive providing guidelines for research on human subjects is not strictly required. The recent Executive Order 12036 states:

"2-302. Restrictions on Experimentation. No agency within the Intelligence Community shall sponsor, contract for, or conduct research on human subjects except in accordance with guidelines issued by the Department of Health, Education and Welfare. The subject's informed consent shall be documented as required by those guidelines."

The principal value of the proposed community directive is the increased visible emphasis it provides on behalf of the Intelligence Community to ensure proper safeguards in the conduct of research on human subjects. The National Commission and the Senate Select Committee on Intelligence have requested copies of our proposed guidelines.

d. The guidelines are general. They supplement the Executive Order in referring to the DHEW Guidelines. They suggest that Intelligence Community agencies publish their own regulations on this subject and emphasize that agency heads are responsible for implementation of the Executive Order. None of the NFIB members suggested that the guidelines not be published. The Department of Energy offered a number of changes which if incorporated would require additional coordination with NFIB members. We believe that those changes not incorporated into the Community directive would be better included in departmental regulations.

3. (U) Recommendation: Approval of proposed [] attached.

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Attachments:

- 1 - Proposed [] Guidelines for Human Subject Research within the Intelligence Community
- 2 - Summary of Agency comments not included in proposed []
- 3 - Comments from NFIB organizations responding to Memorandum for Holders - 2 NFIB-27.7/4, 1 November 1977, "Guidelines for Human Subject Research Within the Intelligence Community"

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CONCUR:

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Deputy to the DCI for Collection Tasking

25 Apr 78
Date

(State & DoE have no objections to how we deal with this information)

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